IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

VELCERA, INC. AND FIDOPHARM, INC.)
Plaintiffs,)
v.)
MERIAL LIMITED,) C.A. No. 11-00134 (GMS)
Defendant,)
and)
MERIAL LIMITED AND BASF AGRO, B.V., ARNHEM (NL), WÄDENSWIL BRANCH,)))
Counterclaim-Plaintiffs,)
v.)
VELCERA, INC. AND FIDOPHARM, INC.,))
Counterclaim-Defendants,	Ć
and)
VELCERA, INC. AND FIDOPHARM, INC.,)))
Counterclaim-Plaintiffs,)
v.)
BASF AGRO, B.V., ARNHEM (NL), WÄDENSWIL BRANCH,))
Counterclaim-Defendant.)

MERIAL LIMITED AND BASF AGRO'S REPLY BRIEF IN SUPPORT OF THEIR MOTION TO DISMISS PLAINTIFFS' DECLARATORY JUDGMENT COMPLAINT

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INTRODUCTION

Contrary to Velcera's¹ inexplicable assertions, there is no question that the United States District Court for the Middle District of Georgia entered a final—not an interlocutory²—order in which it (i) found the PetArmor Plus (fipronil and methoprene containing) product infringes the '329 patent and (ii) enjoined Velcera from selling that product. Since the PetArmor Plus product is enjoined, there is no case or controversy with respect to that product sufficient to support declaratory judgment jurisdiction with respect to any of the patents-in-suit.

In an effort to create a controversy where none exists, Velcera makes a number of misstatements in its opposition to Merial's and BASF's motion to dismiss Velcera's declaratory judgment complaint (D.I. 33). For example, Velcera misstates the scope of the 2011 Georgia Injunction. Specifically, Velcera argues that the 2011 Georgia Injunction does not prohibit it from selling the PetArmor Plus product so long as it is not manufactured or packaged by Cipla. In fact, the Georgia Court explicitly enjoined Velcera from selling the PetArmor Plus products, as well as any other "veterinary products for which Cipla participated in the *development*, manufacture, and/or packaging, which products contain fipronil and methoprene, regardless of brand name" (Ex. 1 at 47 (emphasis added)). Velcera is thus prohibited from selling that product, regardless of who manufactures or packages it, and Velcera cannot avoid the Georgia Court's Order or create a case or controversy simply by switching suppliers.

¹ Merial uses the same defined terms in its reply brief as it did in its opening brief.

² Velcera repeatedly mischaracterizes the 2011 Georgia Injunction as "interlocutory" (D.I. 33 at 2, 4). The Georgia Court, however, clearly directed that its order was a "final judgment . . . entered pursuant to Fed. R. Civ. P. 54(b)" (Ex. 1 at 48).

³ The abbreviation "Ex." refers to the exhibits attached to the Declaration of Jason J. Rawnsley in Support of Merial Limited and BASF Agro's Reply Brief in Support of Their Motion to Dismiss Plaintiffs' Declaratory Judgment Complaint, filed contemporaneously herewith.

Velcera also attempts to create a controversy by asserting that a separate product, called PetArmor (which contains only fipronil as its active ingredient) is also at issue in this action even though (i) nowhere in Velcera's Declaratory Judgment Complaint (D.I. 1) is PetArmor mentioned and (ii) Velcera's CEO—testifying in the Georgia Action—denied that Velcera was selling, or could "in the near future" sell, the PetArmor product. In any event, because the PetArmor product contains only one active ingredient, fipronil, it does not implicate the '329 patent, which requires any infringing product to contain at least two active ingredients, *e.g.*, fipronil and methoprene. Thus, the PetArmor product cannot create a case or controversy as to the '329 patent and this Court, at a minimum, should dismiss all claims with respect to the '329 patent. If the Court concludes that there is a case or controversy regarding any of Velcera's products, Merial submits that the Court should exercise its discretion to dismiss this action.

ARGUMENT

I. There is No Case or Controversy With Regard to the '329 Patent or the PetArmor Plus Product.

A. Velcera Misstates the Scope of the 2011 Georgia Injunction.

Velcera's ability to sell ... PetArmor Plus not sold in concert with Cipla remains entirely unaffected by the [2011 Georgia I]njunction" and that the Georgia Court's injunction "is not a general prohibition onsales [sic] of PetArmor Plus" (D.I. 33 at 11, 14). Velcera reaches this conclusion only by ignoring the text of the 2011 Georgia Injunction, which bars Velcera from selling any fipronil and methoprene containing veterinary product in which Cipla participated in developing, including but not limited to products denominated PetArmor Plus:

Velcera is herewith permanently enjoined from selling, causing to be sold, offering for sale, and causing to be offered for sale in the United States veterinary products for which Cipla participated in the development, manufacture, and/or packaging, which products contain fipronil and methoprene, regardless of brand name, including but not limited to the veterinary products Protektor Plus, PetArmor Plus,

TrustGard Plus, and Velcera Fipronil Plus.

(Ex. 1 at 47-48 (emphasis added).)

Because the Georgia Court—after a two day evidentiary hearing—found that Cipla participated in the development of the PetArmor Plus product, it enjoined Velcera from selling the PetArmor Plus formulation in the United States—regardless of manufacturer (see id. at 14, ¶ 16; 15, ¶ 18; 16, ¶ 20; 18-19, ¶ 24; 39, ¶ 21; 41-42, ¶ 26; 47, ¶ 4). Thus, it is of no moment that Velcera has purportedly "taken steps" to secure an alternative manufacturer for PetArmor Plus (see D.I. 33 at 14; D.I. 35 at ¶ 10), since that product is enjoined, regardless of its manufacturer.

B. Velcera Misstates the Georgia Court's Infringement Finding.

A central mantra of Velcera's brief (see D.I. 33 at 1, 3, 12-13, 16-19)—that it has *not* been found to infringe the '329 patent—is also fundamentally incorrect. The Georgia Court found that Velcera's sale in the United States of the "PetArmor Plus product infringes the '329 Patent" and "PetArmor Plus continues to infringe the relevant claims of Merial's '329 Patent" (Ex. 1 at 35-36, ¶ 16). As the Georgia Court explained:

Velcera acknowledges that PetArmor Plus infringes at least one claim of Merial's '329 Patent, and Cipla makes no credible argument to the contrary. The evidence supports no other conclusion.

(Id. at 17, \P 22; see also id. at 35, \P 16; 19, \P 25.)

Velcera has thus already had its day—in fact *days*—in court to litigate its infringement of the '329 patent.⁵ Tellingly, Velcera presented no evidence that PetArmor Plus did not infringe the

⁴ Velcera also fails to recognize that such a finding was a prerequisite to the Georgia Court's contempt order, since "the party seeking to enforce the injunction must prove *both* that the newly accused product is not more than colorably different from the product found to infringe *and that the newly accused product actually infringes.*" *TiVo, Inc. v. EchoStar Corp.*, No. 2009-1374, 2011 WL 1486162, at *7 (Fed. Cir. April 20, 2011) (emphasis added).

⁵ Once Velcera moved to intervene, it had at least twenty-five days to prepare for the May 16 hearing at which it knew the issue of its contempt, including infringement of the '329 patent by

'329 patent and instead admitted, through its CEO's testimony, that PetArmor Plus did, in fact, infringe the '329 patent (Ex. 2 at 326:3-8). As the Georgia Court acknowledged, it would be "delusional to suggest that no infringement occurred" (Ex. 1 at 18, ¶ 24).

C. Velcera Cannot Collaterally Attack the Validity of the '329 Patent.

As the Georgia Court held, and as explained in Merial's opening brief, Velcera, having voluntarily intervened in the Georgia Action, cannot collaterally attack the validity of the '329 patent⁶ (Ex. 1 at 23, ¶ 4 ("Validity of the patent . . . [is] not open to challenge in the contempt proceedings"; *see also id.* at 34, ¶ 13)). Because Velcera could not attack the '329 patent's validity in the Georgia contempt proceedings, it should not—having now been found in contempt and enjoined in that proceeding—be allowed to collaterally attack the same patent via a declaratory judgment action, the jurisdiction of which is premised on the same enjoined product (see D.I. 31 at 14-15).

Velcera contends that the 1966 amendments to the Federal Rules abrogated the cases on which the Georgia Court and Merial relied for this legal proposition (*see* D.I. 33 at 16-17). As the two cases on which Velcera cites to support its contention show, however, those amendments

PetArmor Plus, would be litigated. Moreover, the Georgia Court has flatly rejected Velcera's assertion that it was sand-bagged by a "flurry of exhibits and witnesses for which Velcera [was] provided no notice" (see D.I. 33 at 8; Ex. 1 at 2, n.2-3). This Court should reject Velcera's efforts to introduce and re-litigate issues already resolved against Velcera.

⁶ Velcera pretends that it did not voluntarily choose to intervene in Georgia contempt proceeding (see D.I. 33 at 15). Velcera, however, correctly concedes in other places that it "chose" to intervene (see id. at 8), and it must therefore accept the consequences of that conscious decision. As a result, Velcera chose Georgia to hear its then-current and now-moot dispute.

⁷ Merial does not contend that Velcera is precluded from ever challenging the validity of the '329 patent. Should a controversy arise in the future with respect to a new fipronil and methoprene containing product, that was not developed with Cipla, then Velcera potentially could bring a declaratory judgment challenging validity of the '329 patent at that time.

merely changed the requirements for allowing a party to intervene as a matter of right—those procedural amendments did not address the legal consequences of such intervention.⁸

Even if Velcera was correct and it is not bound by the Georgia Court's determination of the validity of the '329 patent, the Georgia Court found that Velcera failed to present any credible evidence that the '329 patent is invalid (Ex. 1 at 35, ¶ 16 ("[E]ven if [validity of the '329 Patent] were not established by default, no credible evidence has been presented to establish that the '329 Patent is not valid.")). Thus, while the Georgia Court clearly took the view that Cipla's default (and Velcera's voluntary intervention) removed any issue as to the validity of the '329 patent from the Georgia proceedings. Velcera repeatedly argued against that patent's validity (Ex. 1 at 15-16, ¶ 19; Ex. 2 at 262:2-7, 304:24-305:9, 312:13-22, 325:24-326:8; 327:2-14; 343:25-344:2; Ex. 5 at 154:19-25) and the Georgia Court never restricted Velcera's proof (see Ex. 1 at 35, ¶ 16, Ex. 2 at 82:7-84:21). Velcera did not, however, introduce or proffer any evidence of invalidity and thus waived any challenge to the patent's validity. See U.S. v. Silliman, 167 F.2d 607, 617 (3d Cir. 1948) ("If an issue is raised and the party who has the burden fails in his proof and the issue is decided against him, he is just as much bound by collateral estoppel as though he had presented a barrel of testimony"); see also Matosantos Commercial Corp. v. Applebee's Int'l. Inc., 245 F.3d 1203, 1211 (10th Cir. 2001).

D. Velcera Confuses Collateral Estoppel and Res Judicata With Mootness.

The only question before this Court is whether there is a case or controversy sufficient to meet Article III's requirements. Rather than focusing on that issue, Velcera addresses the issues of collateral estoppel and res judicata, which are irrelevant as to whether a justiciable case or controversy exists (*see* D.I. 33 at 12-13, 15-19). Indeed, the issue here is not whether Velcera was

⁸ The cases Velcera relies on are *U.S. v. Union Elec. Co.*, 64 F.3d 1152, 1161 (8th Cir. 1995) and *Atlantis Dev. Corp. v. U.S.*, 379 F.2d 818, 823-24 (5th Cir. 1967).

afforded the opportunity in the Georgia Action to litigate infringement of the '329 patent⁹ or that patent's validity; instead, the issue is whether there continues to be a real dispute over infringement and validity of the '329 patent following the Georgia Court's June 21 Order without regard to whether those issues were actually litigated in that or any other proceeding. Velcera's repeated references to statements by the Georgia Court to the effect that it was not deciding issues before this Court are thus irrelevant, since the issues of infringement and validity of the '329 patent are not before this Court.

In light of the Georgia Court's June 21 Order enjoining PetArmor Plus, and as demonstrated in Merial's opening brief (D.I. 31 at 10-11), when considering "all the circumstances," there is not a "substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). Although Velcera argues there is a possibility, however remote, ¹⁰ that the Federal Circuit "could" nullify the Order (D.I. 33 at 4-5), the possibility of such an outcome does not equate to there being an immediate case or controversy. *See MedImmune*, 549 U.S. at 126-27 (distinguishing between a declaratory judgment based on a "definite and concrete" case-or-controversy and "an opinion advising what the law would be upon a hypothetical state of facts"); *see also* D.I. 31 at 8-9.

Ontrary to Velcera's arguments, it is estopped from challenging the Georgia Court's infringement determination. See Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc., 458 F.3d 244, 249 (3d Cir. 2006) ("When an issue of fact or law is actually litigated and determined by a valid and final judgment, and the determination is essential to the judgment, the determination is conclusive in a subsequent action between the parties, whether on the same or a different claim." (quoting Restatement (Second) of Judgments § 27 (1982)). Here, with regard to whether the PetArmor Plus products infringe the '329 patent, all four requirements for estoppel are met because Velcera was a fully represented party to the Georgia contempt proceedings and a decision on infringement of the '329 patent was necessary for a finding of contempt. See Henglein v. Colt Indus. Operating Cop., 260 F.3d 201, 209 (3d Cir. 2001); see also n.4, supra.

In light of the 2011 Georgia Injunction, for Velcera to be able to sell a fipronil and methoprene containing animal health product in the United States, it would need to develop a new product formulation, independent of any development efforts by Cipla. Moreover, before Velcera could sell such a new formulation in the United States, it would need to obtain regulatory approval from the EPA, a process which would take many months, more likely years (*see, e.g.,* Exs. 3-4). Rather than attempting to develop a new product formulation without Cipla's aid, Velcera asserts that it "intend[s] to continue to sell fipronil and methoprene products under the PetArmor Plus brand manufactured by another supplier" and has "taken steps to secure an alternative manufacturer" (*see* D.I. 33 at 14; D.I. 35 at ¶ 10). Velcera's sale of the PetArmor Plus products, however, are enjoined by the 2011 Georgia Injunction, since they were co-developed with Cipla. Further, even if such activities were not enjoined, Velcera provides no information as to: (i) what steps it has taken, (ii) whether it has secured an alternative manufacturer, or (iii) when it plans to bring such a product to market (other than in the "future") (*see id.*).

Velcera's uncorroborated speculation about its "new" product is insufficient to satisfy Article III. See, e.g., Telectronics Pacing Sys., Inc. v. Ventritex, Inc., 982 F.2d 1520, 1525-27 (Fed. Cir. 1992) (no controversy of sufficient immediacy and reality to warrant a claim for declaratory relief where new device had only recently begun clinical trials and was not FDA approved); see also Lang v. Pac. Marine & Supply Co., 895 F.2d 761, 764-65 (Fed. Cir. 1990); Amana Refrigeration, Inc. v. Quadlux, Inc., 172 F.3d 852, 855-56 (Fed. Cir. 1999); Serco Servs. Co., L.P. v. Kelley Co., Inc., 51 F.3d 1037, 1038-40 (Fed. Cir. 1995).

Velcera is therefore left to fabricate a controversy where none exists, which it attempts to do by likening this case to situations in which a patent licensee seeks a declaratory judgment against

¹¹ Should Velcera continue its contumacious conduct, it faces sanctions for further contempt of the 2011 Georgia Order, not an action for patent infringement.

the patentee for products the licensee has licensed and is authorized to sell (*see* D.I. 33 at 4). Such a comparison is not instructive. Generally, licensees pay royalties in exchange for limited rights associated with selling patented articles or performing a patented process. Such situations concern licensees who were faced with the dilemma of continuing to pay royalties or, alternatively, facing patent infringement litigation. *See, e.g., MedImmune,* 549 U.S. at 132.

On the other hand, Velcera has no rights in the '329 patent—it is an adjudged infringer that is enjoined from certain activities relating to that patent (see, e.g., Ex. 1 at 16-17, ¶¶ 21-22; 19, ¶ 25; 35, ¶ 16; 41, ¶ 24 and 26; 41-42, ¶ 26; 47-48; D.I. 31 at 4-6). While Velcera may independently develop a fipronil and methoprene product outside the scope of the Georgia Order and file a declaratory judgment action premised on that product, no such product presently exists, and the immediacy and reality requirements necessary to establish a case or controversy are absent. See, e.g., MedImmune, 549 U.S. at 127; Benitec Austl., Ltd. v. Nucleonics, Inc., 495 F.3d 1340, 1344-45 (Fed. Cir. 2007); see also D.I. 31 at 9. This case with respect to the '329 patent and PetArmor Plus is thus moot.

II. Velcera's Allegations With Regard to the PetArmor (Fipronil-Only) Product Do Not Create a Case or Controversy with Respect to the '329 Patent.

During the Georgia proceedings, Velcera's CEO disavowed that Velcera was selling or could sell a PetArmor (fipronil-only) product in the near future (see D.I. 31 at 5, n.7; Ex. 2 at 345:15-346:3). The same individual now testifies that the PetArmor product is at issue in this case (see D.I. 33 at 10-12; D.I. 35 at ¶¶ 7-8). During the conference call with this Court regarding this motion, however, the only product that was identified by Velcera's counsel as being at issue was the PetArmor Plus (fipronil plus methoprene) product—not the PetArmor product—and Velcera even represented that the Court could "put aside those ['848 and '943] patents for now . . ." (see Ex. 6 at 8:25-9:3 and 10:25-11:2). In light of these inconsistencies, and Velcera's failure of proof showing it has sold the PetArmor product from the filing of its declaratory judgment complaint until the

present, the Court should exercise its discretion to dismiss all of Velcera's declaratory judgment claims. *Benitec*, 495 F.3d at 1344-45 (There must be an actual controversy "extant at all stages of review, not merely at the time the complaint [was] filed").

Alternatively, this Court should dismiss the claims relating to the '329 patent. There is no dispute that the PetArmor (fipronil-only) product does not implicate the claims of the '329 patent, and that the claims of the '848 and '943 patents are distinct from those of the '329 patent. Therefore, any case or controversy arising out of Velcera's infringement of the '848 and '943 patents based on the PetArmor product can, and should, be readily segregated from the moot declaratory judgment claims on the '329 patent. See Sierra Applied Scis., Inc. v. Advanced Energy Indus., Inc., 363 F.3d 1361, 1374 (Fed. Cir. 2004) (court must "carefully calibrate" its jurisdictional analysis to each technologically different product).

III. Even if there is Subject Matter Jurisdiction, the Court Should Exercise its Discretion and Decline to Entertain Velcera's Declaratory Judgment Claims With Regard to the '329 Patent.

Should this Court conclude that there is a case or controversy regarding either Velcera's enjoined products (or any hypothetical future fipronil and methoprene product), Merial submits that

¹² The claims of the '848 and '943 patents are directed to industrial processes for manufacturing fipronil, while the claims of the '329 patent are directed to animal health compositions containing pesticides such as fipronil and methoprene (*compare* D.I. 1 Ex. A *with* Exs. C-D).

During both this litigation and the Georgia proceedings, counsel for Velcera acknowledged that the issues with respect to the '848 and '943 patents are distinct from the '329 patent (Ex. 5 at 162:24-163:25; Ex. 6 at 10:25-11:4, 11:22-12:21). Moreover, Velcera represented to both courts its confidence that Merial and BASF will likely voluntarily dismiss the '848 and '943 patents once Velcera discloses its manufacturing process (Ex. 6 at 11:22-12:6; Ex. 5 at 163:18-23). Over five months ago, Merial first requested Velcera disclose its process, but to date Velcera has refused to provide any information on its process (see, e.g., Exs. 8-9). If Velcera is correct, however, the parties should be able to dispose of the claims with regard to the '848 and '943 patents in short order.

the Court should exercise its discretion to decline to retain this case with respect to the '329 patent. See MedImmune, 549 U.S. at 136.

Velcera is not the white knight it portrays itself to be. Velcera, knowing the PetArmor Plus product infringed Merial's '329 patent, violated an existing court order (*i.e.*, the 2008 Georgia Injunction), and proceeded to import, sell, and offer for sale that product in the United States (Ex. 1 at 16-17, ¶¶ 21-22; 19, ¶ 25; 41-42, ¶¶ 24 and 26). Velcera tried to duck the 2008 Georgia Injunction and avoid what it presumably perceived to be an unfriendly venue by bringing this second action with regard to the '329 patent. That attempt failed, and as a result, the Georgia Court has already determined that (i) it has jurisdiction over the first-filed suit with regard to the '329 patent; (ii) the PetArmor Plus product infringes the '329 patent; (iii) the '329 patent is valid; and (iv) Velcera is enjoined from selling the PetArmor Plus product (*see*, *e.g.*, Ex. 1 at 3, n. 3; 35-36, ¶ 16; 47-48). This Court need not, and should not expend its resources to revisit issues, that have already been decided by the Georgia Court and that the Federal Circuit will soon review on appeal. *See Microchip Tech., Inc. v. United Module Corp.*, No. CV-10-04241, 2011 WL 2669627, at *3 (N.D. Cal. July 7, 2011) (judicial efficiency and risk of inconsistent decisions that would arise from multiple litigations on the same issue should not be disregarded lightly).

CONCLUSION

For the reasons and authorities set forth above and in Merial's Opening Brief, Velcera's Declaratory Judgment Complaint and Merial and BASF's counterclaims should be dismissed.

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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I hereby certify that on July 26, 2011, I caused the foregoing document to be electronically filed with the Clerk of Court using CM/ECF, which will send notification of such filing(s) to the registered attorney(s) of record at the addresses, and have sent true and correct copies to the following in the manner indicated below:

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